needs by the attending physician and a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: Laboratory services:* (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) *Standard: Organ procurement.* A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify CMS in writing within 30 days of the termination of the agreement.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988; 57 FR 7134, Feb. 28, 1992; 59 FR 46514, Sept. 8, 1994]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by § 405.2134, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

§ 405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the

sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

§ 405.2184 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply a sanction specified in § 405.2181(b), the following rules apply:

(a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first $100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434 and—